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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/681,753	05/31/2001	James Norman Cawse	RD-28169	6423

6147 7590 03/03/2003

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EXAMINER

CLOW, LORI A

ART UNIT PAPER NUMBER

1631

DATE MAILED: 03/03/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/681,753	Applicant(s) CAWSE, JAMES NORMAN	
	Examiner Lori A. Clow, Ph.D.	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on November 10, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-34 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2 and 3</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

In a telephone conversation on 30 October 2001, Examiner Clow set forth a restriction requirement with applicant's representative, Ben Patel. Mr. Patel faxed in a response to this telephonic restriction requirement on 2 November 2001. Upon further consideration of the claims, the restriction requirement is withdrawn.

Claims 1-34 are currently pending.

Claim Rejections - 35 USC § 112

Claims 1-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

In considering the factors for the instant claims:

a) In order to practice the claimed invention one of skill in the art must be able to conduct an experiment by selecting factors, estimating interactions, assigning probabilities, effecting a combinatorial high throughput screen, and adjusting the probabilities for each interaction

according to the results. For the reasons discussed below, this constitutes undue experimentation.

b) The specification provides no guidance regarding the factors that should be selected, how estimations are performed, how probabilities are assigned or adjusted.

c) The specification provides a working example of a non-defined chemical space (Table I and Table II). However, this does not provide a means for which to practice said invention. Furthermore, no active steps are provided that would direct one to conduct an experiment according to the claims.

Base claims 1 and 27 require one to select factors for an experiment. However, there is no guidance as to what factors should be used or considered for said experiment. Furthermore, there is no guidance as to how to estimate interactions among levels of the factors and then assign a probability value indicating a positive interaction. The next requirement is that a combinatorial high throughput screening method be effected. However, there are no guidelines to practice this step. There is no definition of what "effecting" a CHTS method means. The claims require an experimental space, however, the specification does not set forth any steps or methods to ascertain or set up an experimental space. Finally, probabilities should be adjusted for the interactions. How are these to be adjusted? Furthermore, what does the adjustment ultimately achieve? The preamble requires the implementation of a method to conduct an experiment. No experiment is conducted in the steps of base claim 1.

Absent clear and illustrative guidance as to how to particularly perform the above invention, there would be undue experimentation required in order to practice the specific steps of the invention.

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d) The invention is drawn to a method to conduct an experiment. However, no steps are provided to do so.

e) and g) It would have been well known in the art that systems to conduct combinatorial experiments through high throughput were available. For instance, Ghose et al. (Journal of Combinatorial Chemistry (1999) Vol.1:55-68) describe approaches to designing combinatorial libraries for drug discovery. This approach utilizes molecular databases, physiochemical properties of molecules, profiling, comparisons and analysis of chemical functionalities. Numerous other systems and techniques such as QSAR, COMMA, and COMFA methods are well known in the art. However, absent specific, illustrative guidance in the specification, the instant claims are not enabled. There is no guidance on how to perform the selecting, estimating, assigning, and adjusting steps.

h) The claims are broad because they are not limited to any particular factors, values, screening methods, adjustments. While some claims are directed to factors such as catalyst metals (claim 21, for example), there are still no steps that would explain or define how to estimate interactions between those given factors.

The skilled practitioner would first turn to the instant specification for guidance to practice methods of conducting a high throughput experiment. However, the instant specification does not provide specific guidance to practice these embodiments. As such, the skilled practitioner would turn to the prior art for such guidance. The prior art describes numerous techniques available to practice the high throughput technology. However, the specification lacks the guidance to implement such broad claims. Finally, said practitioner

would turn to trial and error experimentation to determine the various parameters necessary to practice said invention. Such represents undue experimentation.

Claims 10 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 10 and 11 lack antecedent basis. Claim 1 refers to a method to conduct an experiment. However, claim 1 does not include generation of a model, as required by claims 10 and 11.

No claims are allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (703) 306-5439. The examiner can normally be reached on Monday-Friday from 10am to 6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

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PRIMARY EXAMINER
GROUP 1800
Art 1631

February 27, 2003

Lori A. Clow, Ph.D.

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Lori A. Clow